IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB Bank, N.A., as Trustee, Plaintiff, - against - SANOFI, Defendant.	No. 15 Civ. 08725 (GBD) (RWL)

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AS TO COUNTS I, II AND VII OF THE SECOND AMENDED COMPLAINT

CAHILL GORDON & REINDEL LLP
Charles A. Gilman
Tammy L. Roy
Jonathan D. Thier
Michael B. Weiss
Adam S. Mintz
Brent L. Andrus
Margaret A. Barone
Caroline Saucier
80 Pine Street
New York, New York 10005
(212) 701-3000

Attorneys for Plaintiff UMB Bank, N.A., as Trustee

September 13, 2019

TABLE OF CONTENTS

Page(s)

GLOSSARY OF DEFINED TERMS 1

I. PROCEDURAL HISTORY AND BACKGROUND 1

A. The Parties 4

B. The Acquisition and CVR Agreement 5

C. The CVR Milestones and Sanofi's Efforts Obligations to Achieve Them 9

D. Sanofi's Obligations to Bayer Under the CVR Agreement 15

E. Lemtrada® Drug Background 16

F. Sanofi Personnel 19

II. SANOFI EXECUTIVES IGNORED OR WERE NOT AWARE OF THEIR OBLIGATIONS UNDER THE CVR AGREEMENT 23

III. SANOFI CALCULATED LEMTRADA®'S PROFITABILITY BY INCLUDING BOTH THE BAYER ROYALTY AND CVR MILESTONE PAYMENTS AND CONSIDERED THESE CALCULATIONS WHEN CUTTING LEMTRADA®'S BUDGET. 26

A. After the Merger, Sanofi Imposed Budget Cuts Rather than Invest in Developing Lemtrada®'s Market Potential 29

B. [redacted] 32

C. Sanofi Continued to Cut the Budget for Lemtrada® in 2013 and 2014 39

IV. SANOFI REJECTED OR BLOCKED INVESTMENTS PREVIOUSLY PLANNED BY GENZYME FOR THE DEVELOPMENT OF LEMTRADA® 42

A. Life Cycle Management Is a Well-Accepted Aspect of the Pharmaceutical Business, Required to Build and Maintain a Profitable Product 42

B. Life Cycle Management Requires Investment to Capture Market Potential for a Drug 44

C. PPMS is a Subset of MS Which Was a Promising Treatment Segment for Lemtrada®, but [redacted] 45

D. [redacted] 48

E. [redacted] 49

F. [redacted] 50

V. SANOFI MADE MULTIPLE ERRORS IN SEEKING FDA APPROVAL FOR LEMTRADA®, CAUSING THEM TO RECEIVE BOTH A REFUSE TO FILE AND COMPLETE RESPONSE LETTER FROM THE FDA AND MISS THE APPROVAL MILESTONE 51

A. Phase III Clinical Trials for Lemtrada® Produced [redacted] Results, After Which Sanofi Prepared to Submit Its Application to the FDA for Approval of Lemtrada in MS 52

B. Sanofi Submitted Its Application to the FDA for Lemtrada® but It Was Rejected Due to Biostatistics Concerns 53

C. [redacted] 58

D. [redacted] 59

E. [redacted] 64

VI. THE COMMERCIALIZATION AND LAUNCH OF LEMTRADA® SHOWED A LACK OF DILIGENT EFFORTS AND, IN FACT, SHOWED A CONCERTED DESIRE TO AVOID PRODUCT SALES MILESTONE #1 66

A. [redacted] 67

B. [redacted] 71

C. [redacted] 72

D. [redacted] 75

E. [redacted] 78

F. [redacted] 80

G. [redacted] 84

H. [redacted] 86

I. [redacted] 87

VII. IN THE MONTHS AFTER THE MERGER, SANOFI DELAYED TAKING ANY ACTIONS TOWARD ACHIEVING THE PRODUCTION MILESTONE, CAUSING SANOFI TO MISS THIS TARGET 89

A. Fabrazyme® and Cerezyme® Background Information 89

B. Sanofi Knew of Manufacturing Issues with Cerezyme® and Fabrazyme® Prior to the Merger 91

C. [redacted] 93

GLOSSARY OF DEFINED TERMS

ABM	means "Area Business Manager," a sales and marketing role.
AIF	means "Autorisation D'Investissement Financier" (Financial Investment Authorization), an integrated process and system to serve decision making at ExCom level on financial investments.
Alemtuzumab	means Lemtrada®.
Align to WinS	refers to a resource allocation and optimization program targeting operational expenses.
Answer	refers to Sanofi's September 29, 2017 Answer to the Second Amended Complaint.
Approval Milestone	refers to the CVR Agreement provision that entitles CVR holders to receive $1 per CVR after "receipt by the Company or one of its Affiliates, on or before March 31, 2014, of the FDA Approval of alemtuzumab for treatment of multiple sclerosis."
AST	refers to the American Stock Transfer & Trust Company, LLC.
Aubagio®	refers to teriflunomide, a pyrimidine sythesis inhibitor indicated for the treatment of patients with relapsing multiple sclerosis.
Bayer Royalty, Bayer Liability	Sanofi's obligations to Bayer under Genzyme's prior License and Asset Purchase Agreement.
Bayer, BSP	refer to Bayer Schering Pharma AG.
BLA	means a "Biologics License Application," the application for FDA approval of a new biologic product.
BOI	means "Business Operating Income," Sanofi's metric for tracking and reporting the profitability of its products.
BRM	means "Business Relationship Manager," a sales and marketing role.
Breach Interest Rate	means the interest rate to be applied to payments due to the CVR holders in the event of a breach as defined in the CVR Agreement § 1.1.

CAMMS 323	Refers to the Phase III study protocol for Alemtuzumab in naïve patients with Relapsing-Remitting Multiple Sclerosis.
CAMMS 324	Refers to the Phase III study protocol for Alemtuzumab in relapsed patients with Relapsing-Remitting Multiple Sclerosis.
CEO	means Chief Executive Officer.
Cerezyme®	refers to imiglucerase, a recombinant enzyme replacement for the treatment of Gaucher disease.
CFO	means Chief Financial Officer.
COGS	means "Cost Of Goods Sold."
COMEX, ExCom	refer to Sanofi's Executive Committee.
commercially reasonable efforts	refers to the required obligation of effort with respect to the Production Milestone as set forth in the CVR Agreement § 7.10.
Complaint	refers to the complaint filed by AST on November 9, 2015.
CRL	refers to the FDA's "Complete Response Letter."
CVR	refers to a Contingent Value Right, an instrument requiring an acquirer to pay additional consideration to the holder upon the occurrence of specified triggering events.
CVR Agreement	refers to the Contingent Value Rights Agreement by and between Sanofi-Aventis and American Stock Transfer & Trust Company, LLC, Dated as of March 30, 2011.
CZ	means Cerezyme®.
Diligent Efforts	refers to the required obligation of effort with respect to the Approval Milestone and Product Sales Milestones as set forth in the CVR Agreement § 7.10.
DVS	means "Disability Verification Study"
ECTRIMS	refers to the "European Committee for Treatment and Research In Multiple Sclerosis," an organization that holds annual industry conferences concerning MS.

EDSS	refers to the Expanded Disability Status Scale, a subjective measurement used to assess the health of a patient with multiple sclerosis.
Fabrazyme®	refers to agalsidase beta, a recombinant enzyme replacement therapy for the treatment of Fabry Disease.
FDA	refers to the U.S. Food and Drug Administration.
Framingham	refers to Genzyme's biologics manufacturing facility in Framingham, Massachusetts.
Genzyme	refers to Genzyme Corporation, a biotechnology corporation acquired by Sanofi in 2011 and now a wholly-owned subsidiary of Sanofi.
Gilenya®	refers to fingolimod, a treatment for relapsing MS.
HCP	means "Healthcare Provider."
ISM	means "Infusion Support Manager," a specialist in the infusion of treatments that supports healthcare providers.
LAPA	refers to the License and Asset Purchase Agreement dated March 30, 2009, between Genzyme and Bayer.
LCM	means "Life Cycle Management," the process of creating a plan to ensure the long-term success over the life cycle of a product.
Lemtrada®	refers to alemtuzumab, a CD52-directed cytolytic monoclonal antibody for the treatment of relapsing multiple sclerosis.
LRP	means "Long Range Plan."
Merger Agreement	refers to the February 16, 2011 Agreement and Plan of Merger among Sanofi-Aventis, GC Merger Corp. and Genzyme Corporation.
Milestone Payments	refers to the payments for any of the CVR Agreement Milestones as defined in the CVR Agreement.
Milestone(s)	refers to the triggering events for a payment to holders under the CVR Agreement, specifically, any of the Approval Milestone, Product Sales Milestones, and the Production Milestone.
MRI	means "Magnetic Resonance Imaging."

MS	refers to multiple sclerosis, a disease of the central nervous system.
MS BU	refers to Genzyme's Multiple Sclerosis Business Unit.
MS STAR	refers to Multiple Sclerosis Strategic Therapeutic Area Review.
MSOC	refers to Genzyme's "Manufacturing & Strategic Operations Committee."
NASDAQ	means the Nasdaq stock exchange.
NPV	means "Net Present Value."
Ocrevus®	refers to ocrelizumab, the first FDA-approved drug for the treatment of PPMS.
OPEX	means "Operating Expenses."
PPA	means "Purchase Price Allocation," a valuation exercise.
PPMS	means "Primary Progressive Multiple Sclerosis," a subset of multiple sclerosis distinct from relapsing forms of multiple sclerosis.
Product Sales Milestone #1	refers to the CVR Agreement provision that entitles CVR holders to receive $2 per CVR in the event "the sum of (x) the aggregate Major Market Product Sales for each Qualifying Major Market plus (y) the aggregate Product Sales achieved in all countries that are not Qualifying Major Markets during the four (4)-calendar quarter period that begins on the first anniversary of Product Launch equals or exceeds a total of four hundred million dollars."
Product Sales Milestone #2	refers to the CVR Agreement provision that entitles CVR holders to receive $3 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of one billion eight hundred million dollars."
Product Sales Milestone #3	refers to the CVR Agreement Provision that entitles CVR holders to receive $4 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of two billion three hundred million dollars."

Product Sales Milestone $4	refers to the CVR Agreement Provision that entitles CVR holders to receive $3 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of two billion eight hundred million dollars."
Product Sales Milestones	means each of (a) Product Sales Milestone #1, (b) Product Sales Milestone #2, (c) Product Sales Milestone #3 and (d) Product Sales Milestone #4.
Production Milestone	refers to the CVR Agreement provision that entitles CVR holders to receive $1 per CVR in the event that Cerezyme® and Fabrazyme® production levels achieve certain thresholds in calendar year 2011.
PSM #1	means Product Sales Milestone #1.
PSM #2	means Product Sales Milestone #2.
PSM #3	means Product Sales Milestone #3.
PSM #4	means Product Sales Milestone #4.
R&D	means "Research and Development."
REMS	means Risk Evaluation and Mitigation Strategy, a risk mitigation prescribing program that can be required by the FDA.
RRMS	means "Relapsing-Remitting Multiple Sclerosis."
RTF	refers to a "Refuse to File" letter from the FDA.
SAD	means "Sustained Accumulation of Disability."
Sanofi	refers to refers to Sanofi, a multinational pharmaceutical company incorporated under the laws of France as a *société anonyme.*
sBLA	means a "supplemental Biologics License Application," the application for FDA approval of a biologic product with already-approved biosimilars.
SEC	refers to the U.S. Securities and Exchange Commission.
Second Amended Complaint	refers to the second amended complaint filed August 29, 2017 in this litigation.

SKP	means "Simon-Kucher & Partners," a consulting firm.
Teriflunomide	means Aubagio®.
TLL	means "Thought Leader Liason," a role tasked with improving marketing operations and resolving customer issues.
Trustee	after June 30, 2016, refers to UMB Bank, N.A., a federally-chartered national banking organization with a principal place of business in Kansas City, Missouri, and before June 30, 2016 refers to the American Stock Transfer & Trust Company, LLC.
Tysabri®	refers to natalizumab, a treatment for *inter alia*, Multiple Sclerosis.
UMB Bank, N.A.	refers to UMB Bank, N.A., a federally-chartered national banking organization with a principal place of business in Kansas City, Missouri.
VP	means Vice President.

Pursuant to Local Civil Rule 56.1, Plaintiff UMB Bank, N.A. as Trustee ("Trustee") submits this statement of material facts as to which there is no genuine issue to be tried in support of its Motion for Summary Judgement as to Counts I, II and VII of the Second Amended Complaint.[1]

I. Procedural History and Background

1. **This action was instituted by a Complaint filed by American Stock Transfer & Trust Company, LLC ("AST") on November 9, 2015.** *See* Complaint at 1 (ECF No. 5).

2. **The Complaint filed by AST contains three causes of action:**

- **Count I – Breach of Contract for Failure to use Diligent Efforts to meet the Approval Milestone;**
- **Count II – Breach of Contract for Failure to use Diligent Efforts to meet the Product Sales Milestones; and**
- **Count III – Breach of the Implied Covenant of Good Faith and Fair Dealing.**

See Complaint at 34-36 (ECF No. 5).

3. **On May 13, 2016, AST tendered its resignation as Trustee.** *See* Ex. 301, Instrument of Appointment and Acceptance at 1 (ECF No. 54-1).

4. **On June 30, 2016, UMB Bank, National Association ("UMB") accepted appointment as Trustee under the CVR Agreement.** *See* Ex. 301, Instrument of Appointment and Acceptance at 1 (ECF No. 54-1).

5. **AST's resignation as Trustee under the CVR Agreement became effective on June 30, 2016.** *See* Ex. 301, Instrument of Appointment and Acceptance at 1 (ECF No. 54-1).

[1] Unless otherwise indicated, the exhibits cited herein are attached to the Declaration of Adam S. Mintz dated September 13, 2019, and filed concurrently herewith.

6. **On July 8, 2016, UMB filed an unopposed Motion to Substitute Party pursuant to Rule 25(c) of the Federal Rules of Civil Procedure.** *See* Motion to Substitute Party at 1 (ECF No. 56).

7. **On July 19, 2016, the Court granted the Motion to Substitute Party.** *See* Order granting Motion to Substitute Party at 1 (ECF No. 66).

8. **On January 29, 2016, Sanofi moved to dismiss Counts II and III of the Complaint.** *See* Notice of Defendant's Motion to Dismiss Counts II and III of the Complaint at 1 (ECF No. 19).

9. **On September 8, 2016, the Court denied Sanofi's motion to dismiss Count II as to breach of contract regarding Product Sales Milestone #1**. *See* Memorandum Decision and Order at 16 (ECF No. 76).

10. **As to breach of contract claims for Product Sales Milestones #2-4, the Court ruled that "as the deadline to meet those milestones is not until December 31, 2020," those claims are not yet ripe.** *See* Memorandum Decision and Order at 12, n. 6 (ECF No. 76).

11. **A Second Amended Complaint was filed by UMB on August 29, 2017.** *See* Second Amended Complaint at 1 (ECF No. 125).

12. **The Second Amended Complaint contains seven causes of action:**

- **Count I – Breach of Contract for Failure to use Diligent Efforts to meet the Approval Milestone;**
- **Count II – Breach of Contract for Failure to use Diligent Efforts to meet the Product Sales Milestones;**
- **Count III – Breach of the Implied Covenant of Good Faith and Fair Dealing;**
- **Count IV – Declaratory Judgment against Sanofi requiring reimbursement of Trustee fees and expenses;**

- **Count V – Declaratory Judgment against Sanofi for failure to comply with Trustee's requests pursuant to Sections 4.2(f) and 5.4(b) of the CVR Agreement;**

- **Count VI – Declaratory Judgment against Sanofi for failure to comply with the Trustee's request, on behalf of Acting Holders, pursuant to Section 7.6(a) of the CVR Agreement;**

- **Count VII – Breach of Contract for failure to use Commercially Reasonable Efforts to meet the Production Milestone on a timely basis.**

See Second Amended Complaint at 61-68 (ECF No. 125).

13. **Sanofi filed an Answer to the Second Amended Complaint on September 29, 2017.** *See* Answer to the Second Amended Complaint at 1 (ECF No. 132).

14. **On October 6, 2017, Plaintiff filed a Motion for Summary Judgment as to Count VI of the Second Amended Complaint for declaratory judgment to compel Sanofi to submit to an independent audit of its Product sales statements and the figures underlying the Calculations set forth therein.** *See* Motion for Summary Judgment at 1 (ECF No. 134).

a. **The CVR Agreement requires periodic reporting by Sanofi and entitles the Trustee to have an independent accountant verify the accuracy of the Product Sales information provided by Sanofi.** *See* Ex. 1, Contingent Value Rights Agreement by and between Sanofi-Aventis and American Stock Transfer & Trust Company, LLC ("CVR Agreement") § 7.6 (ECF No. 1-1).

b. **Sanofi recognized this ongoing reporting obligation and the Trustee's right to have an independent accountant verify the accuracy of the product sales information provided by Sanofi in its Form F-4 Registration Statement.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 85 (Mar. 7, 2011).

15. **A Memorandum Decision and Order was issued on May 29, 2018 by Judge George B. Daniels, adopting the Report and Recommendation of Magistrate Judge Robert W. Lehrburger, and granting Plaintiff's Motion for Summary Judgment as to the audit request under Count VI of the Second Amended Complaint, but directing that the start of the audit be deferred during discovery in the litigation.** *See* Memorandum Decision and Order at 8 (ECF No. 195).

A. The Parties

16. **UMB is a federally-chartered national banking organization with a principal place of business in Kansas City, Missouri.** *See* Ex. 2, Our History, UMB Financial Corporation Website at 1, available at https://www.umb.com/personal/aboutumb/company/our-history (last visited Aug. 28, 2019).

17. **UMB is the successor trustee under the CVR Agreement.** *See* Ex. 301, Instrument of Appointment and Acceptance at 1 (ECF No. 54-1); *see* Motion to Substitute Party at 1 (ECF No. 56); *see* Order granting Motion to Substitute Party at 1 (ECF No. 66).

18. **UMB is vested "with all the rights, powers, trusts and duties" under the CVR Agreement.** CVR Agreement § 4.11(a).

19. **UMB is a party to the CVR Agreement.** *See* Ex. 301, Instrument of Appointment and Acceptance at 1 (ECF No. 54-1)

20. **Sanofi S.A. ("Sanofi") is a French multinational pharmaceutical company engaged in the research and development, manufacturing, and marketing of pharmaceutical drugs.** *See generally* Ex. 3, *About Us*, SANOFI WEBSITE, available at https://www.sanofi.com/en/about-us/sanofi-at-a-glance (last visited July 31, 2019).

21. **Sanofi is headquartered in Paris, France.** *See generally* Ex. 4, *Investors Contacts*, SANOFI WEBSITE, available at https://www.sanofi.com/en/investors/contact (last visited Aug. 28, 2019).

22. **Sanofi is a party to the CVR Agreement.** *See* Ex. 1, CVR Agreement at 1.

23. **The CVR Agreement defines an Affiliate of Sanofi, in part, as "any other Person directly or indirectly controlling or controlled by or under direct or indirect common control with such specified Person."** Ex. 1, CVR Agreement § 1.1, definition of "Affiliate."

24. **Genzyme, a wholly owned subsidiary of Sanofi, is an Affiliate of Sanofi.** *See generally* Ex. 5, *About Us*, SANOFI GENZYME WEBSITE, available at https://www.sanofigenzyme.com/en/about-us (last visited Aug. 28, 2019).

B. The Acquisition and CVR Agreement

25. **On July 29, 2010, Sanofi made an unsolicited offer of $69 cash per share to acquire Genzyme, a U.S. biotech company.** *See* Ex. 6, *Genzyme Confirms Receipt of Unsolicited Proposal*, SANOFI GENZYME WEBSITE at 2 (Aug. 30, 2010), available at https://www.sanofigenzyme.com/en/about-us/newsroom/archive/2010/2010-08-30-07-37-00; Ex. 7, SAN-CVR 017217439 at 443.

26. **On August 29, 2010, Sanofi sent Genzyme a letter proposing $69 cash per share to acquire Genzyme.** *See* Ex. 6, *Genzyme Confirms Receipt of Unsolicited Proposal*, SANOFI GENZYME WEBSITE at 2 (Aug. 30, 2010), available at https://www.sanofigenzyme.com/en/about-us/newsroom/archive/2010/2010-08-30-07-37-00.

27. **On August 30, 2010, Genzyme's board of director unanimously rejected Sanofi's offer as inadequate.** *See* Ex. 6, *Genzyme Confirms Receipt of Unsolicited Proposal*,

SANOFI GENZYME WEBSITE at 2 (Aug. 30, 2010), available at https://www.sanofigenzyme.com/en/about-us/newsroom/archive/2010/2010-08-30-07-37-00.

28. **In the following months, Sanofi and Genzyme continued to negotiate until an agreement was reached for $74 per share in addition to a Contingent Value Right ("CVR").** *See* Ex. 9, SAN-CVR 013900091 at 091; *See* Ex. 8, Genzyme Corporation, Schedule 14D-9, Solicitation/Recommendation Statement Pursuant to Section 14(d)(4) of the Securities Exchange Act of 1934 ("Genzyme Schedule 14D-9") at 13-19 (Mar. 7, 2011), available at https://www.sec.gov/Archives/edgar/data/732485/000095012311022458/b85369sc14d9za.htm.

29. **The CVR was intended to bridge the gap in Sanofi and Genzyme's valuation difference.** *See* Ex. 8, Genzyme Schedule 14D-9 at 13-19.

30. **The parties' difference relating to the valuation of Genzyme was largely attributable to two matters:**

- **First, Genzyme thought that Lemtrada® (alemtuzumab), a drug that at the time had already been approved by the FDA as a leukemia treatment, would be approved by the FDA for the treatment of relapsing remitting multiple sclerosis and would be a blockbuster drug.**
- **Second, Genzyme anticipated that the production problems with their drugs Cerezyme® and Fabrazyme® would be resolved, leading to increased production of both drugs.**

See Ex. 8, Genzyme Schedule 14D-9 at 13-19.

31. **The Agreement and Plan of Merger was signed on February 16, 2011.** *See* Ex. 10, Agreement and Plan of Merger among Sanofi-Aventis, GC Merger Corp. and Genzyme Corporation at 1 (Feb. 16, 2011), available at https://www.sec.gov/Archives/edgar/data/732485/000095012311014482/b85002exv2w1.htm.

32. **By April 1, 2011, Sanofi had purchased 84.6% of Genzyme's outstanding shares to effectuate the merger.** *See* Ex. 11, *Sanofi-Aventis Successfully Completes Exchange Offer for Genzyme Corporation*, PR NEWSWIRE at 1 (Apr. 4, 2011), available at https://www.prnewswire.com/news-releases/sanofi-aventis-successfully-completes-exchange-offer-for-genzyme-corporation-119161914.html.

33. **The total cash price was over $20 billion.** *See* Ex. 12, *Sanofi to Buy Genzyme for more than $20 Billion*, REUTERS at 1 (Feb. 16, 2011), available at https://www.reuters.com/article/us-genzyme-sanofi-idUSTRE71E4XI20110216.

34. [redacted]

35. **Genzyme shareholders received $74 cash and one CVR per share tendered or exchanged in the merger.** *See* Ex. 14, Sanofi's Prospectus Filed Pursuant to Rule 424(b)(3) at 1, available at https://www.sec.gov/Archives/edgar/data/1121404/000119312511082363/d424b3.htm (last visited Sept. 3, 2019).

36. **Approximately 291,431,450 CVRs were issued as part of the total transaction consideration by Sanofi to Genzyme shareholders.** *See* Ex. 15, SAN-CVR 022060930 at 930.

37. **On March 30, 2011, Sanofi-Aventis and American Stock Transfer & Trust Company, LLC entered into the Contingent Value Rights Agreement (the "CVR Agreement").** *See* Ex. 1, CVR Agreement at 1.

38. **In the Schedule 14D-9 filed with the Securities and Exchange Commission on March 7, 2011 and published to its shareholders, Genzyme estimated the value of each CVR**

at $5.58, as of March 2011, and recommended that its shareholders approve the merger. *See* Ex. 8, Genzyme Schedule 14D-9 at 19.

a. [redacted]

b. [redacted]

c. **Christopher Viehbacher testified that, at the time the merger was approved, Sanofi "ascribed very high probability to the approval milestone and a high probability to the first sales milestone of $400 million."** Ex. 26, August 29, 2018 Videotaped Deposition of Christopher Viehbacher ("Viehbacher Dep. Tr.") at 59:5-59:13.

d. **In its March 7, 2011 Form F-4 Registration Statement, Sanofi incorporated by reference Genzyme's "description of the consideration" afforded by the CVRs.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at iii (Mar. 7, 2011) (Sanofi incorporated Genzyme's Schedule 14D-9 by reference in its Form F-4 Registration Statement).

e. **In its Form F-4 Registration Statement, Sanofi also stated that the CVRs provided Genzyme shareholders "the opportunity to participate in any future success of Lemtrada and the production in 2011 of both Cerezyme and Fabrazyme."** Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at v (Mar. 7, 2011).

f. **A probable value of $5.58 for each of the 291.4 million CVRs represents a total CVR value of over $1.6 billion.** *See* Ex. 16, DP_Sanofi_0001792 at 792.

39. **This Schedule 14D-9 also estimated 90% probability of achieving the Approval Milestone.** *See* Ex. 8, Genzyme Schedule 14D-9 at 42.

40. **This Schedule 14D-9 also estimated a 80% likelihood of achieving Product Sales Milestone #1.** *See* Ex. 8, Genzyme Schedule 14D-9 at 42.

41. **This Schedule 14D-9 was among the materials published to shareholders seeking approval for the merger.** *See generally* Ex. 8, Genzyme Schedule 14D-9; *see* Ex. 17, SAN-CVR 013574104 at 157.

42. **The CVR Agreement is governed by New York law.** *See* Ex. 1, CVR Agreement § 1.10.

43. **The CVRs are securities, and are listed for trading on NASDAQ.** *See* Ex. 1, CVR Agreement § 7.7.

44. **Breach Interest Rate is defined in the CVR Agreement as the interest rate to be applied to payments due to the CVR holders in the event of a breach, as defined in the CVR Agreement § 1.1.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Breach Interest Rate"; § 8.1.

45. **Breach Interest Rate is defined to mean**

> **"a per annum rate equal to the prime rate of interest quoted by Bloomberg, or similar reputable data source, plus three percent (3%), calculated daily on the basis of a three hundred sixty-five (365) day year or, if lower, the highest rate permitted under applicable law."**

Ex. 1, CVR Agreement § 1.1, definition of "Breach Interest Rate."

C. The CVR Milestones and Sanofi's Efforts Obligations to Achieve Them

46. **The CVR Agreement contains six Milestones.** *See* Ex. 1, CVR Agreement § 1.1.

47. **The Approval Milestone entitles CVR holders to receive $1 per CVR after "receipt by the Company or one of its Affiliates, on or before March 31, 2014, of the FDA Approval of alemtuzumab for treatment of multiple sclerosis."** Ex. 1, CVR Agreement § 1.1, definition of "Approval Milestone", "Approval Milestone Payment."

a. **In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for the Approval Milestone.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

b. **The latest payment date for the Approval Milestone is 20 business days after notice of achievement of such milestone.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

48. **Product Sales Milestone #1 ("PSM#1") entitles CVR holders to receive $2 per CVR in the event "the sum of (x) the aggregate Major Market Product Sales for each Qualifying Major Market plus (y) the aggregate Product Sales achieved in all countries that are not Qualifying Major Markets during the four (4)-calendar quarter period that begins on the first anniversary of Product Launch equals or exceeds a total of four hundred million dollars."** Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #1", "Product Sales Milestone Payment."

a. **In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for PSM#1.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

b. **The latest payment date for PSM#1 is 20 business days after notice of achievement of such milestone.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

49. **Product Sales Milestone #2 ("PSM#2") entitles CVR holders to receive $3 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of one billion eight hundred million dollars."** Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #2", "Product Sales Milestone Payment."

a. **Product sales for PSM#1 may be used as well for PSM#2, but any quarters used for the achievement of PSM#2 cannot be used again for the achievement of any subsequent milestone.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #2."

b. **If PSM#2 is achieved despite the Approval Milestone not having occurred, the CVR holders are entitled to an additional $1 per CVR.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone Payment."

50. **Product Sales Milestone #3 ("PSM#3") entitles CVR holders to receive $4 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of two billion three hundred million dollars."** Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #3", "Product Sales Milestone Payment."

a. **No Product Sales that occur in quarters used to achieve PSM#1 or PSM#2 can be used again for the achievement of PSM#3.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #3."

51. **Product Sales Milestone #4 ("PSM#4") entitles CVR holders to receive $3 per CVR in the event "Product Sales in any Product Sales Measuring Period are equal to or in excess of two billion eight hundred million dollars."** Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #4", "Product Sales Milestone Payment."

a. **No Product Sales that occur in quarters used to achieve PSM#1, PSM#2, or PSM#3 can be used again for the achievement of PSM#4.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #4."

52. **The Production Milestone entitles CVR holders to receive $1 per CVR in the event that Cerezyme® and Fabrazyme® production levels achieve certain thresholds in calendar year 2011.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Production Milestone", "Production Milestone Payment."

a. **In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for the Production Milestone.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

b. **The latest payment date for the Production Milestone is 20 business days after notice of achievement of such milestone.** *See* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 81 (Mar. 7, 2011).

53. **If all six milestones were achieved, the CVR Agreement required Sanofi to pay a total of $14 cash per CVR to the Trustee for the benefit of the CVR holders.** *See* Ex. 1, CVR Agreement § 1.1.

54. **If all six milestones were achieved and all CVRs initially issued remained outstanding at the time payment was due, the CVR Agreement would have required Sanofi to pay a total of approximately $4,102,000,000.** *See* Ex. 1, CVR Agreement § 1.1; *See* Ex. 17, SAN-CVR 013574104 at 197.

55. **This potential $4.1 billion payment equals 20% of the total purchase price.** *See* Ex. 12, *Sanofi to Buy Genzyme for more than $20 Billion*, REUTERS at 1 (Feb. 16, 2011), available at https://www.reuters.com/article/us-genzyme-sanofi-idUSTRE71E4XI20110216.

56. **The CVR Agreement obligates Sanofi to "use Diligent Efforts to achieve the Approval Milestone and the Product Sales Milestones."** Ex. 1, CVR Agreement § 7.10.

57. **The phrase Diligent Efforts is defined in the CVR Agreement as:**

> **"Diligent Efforts' means, with respect to the Product, efforts of a Person to carry out its obligations, and to cause its Affiliates and licensees to carry out their respective obligations, using such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity, product profile, including efficacy, safety, tolerability and convenience, the competitiveness of alternate products in the marketplace or under development, the availability of existing forms or dosages of alemtuzumab for other indications, the launch or sales of a biosimilar product, the regulatory environment and the profitability of the applicable product (including pricing and reimbursement status achieved) consistent with the Company's publicly reported financial statements (assuming the Company will not treat royalty payments to BSP as an expense for purposes of this clause, or the achievement of Milestones in such a manner, that would reduce the profitability of the Product), and other relevant factors, including technical, commercial, legal, scientific and/or medical factors. Subject to the foregoing, "Diligent Efforts" shall include, but shall not be limited to, the following: (a) making expenditures in relation to the Product that are consistent with expenditures normally made by Persons in the pharmaceutical business in connection with products of similar market potential at similar stages in their development or product life; (b) implementing and maintaining appropriate Product and patient support services (including, but not limited to, risk identification and minimization programs and reimbursement support services); (c) initiating and completing all post-marketing approval commitments; (d) promptly seeking pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets; (e) fulfilling obligations under any co-promotion agreement or arrangement with BSP should BSP exercise its right to co-promote the Product; (f) setting or seeking a commercial price for the Product that is consistent with the profile of the Product, including seeking premium pricing based on the effectiveness of the Product; (g) promoting the Product for all labeled multiple sclerosis indications; and (h) otherwise fulfilling the obligations of the Company and its Affiliates under Existing Licenses, including fulfilling obligations pursuant to the LAPA in order to maintain the rights to develop and commercialize the Product granted thereunder."**

Ex. 1, CVR Agreement § 1.1, definition of "Diligent Efforts."

58. **The CVR Agreement obligates Sanofi to "use commercially reasonable efforts to achieve the Production Milestone on a timely basis."** Ex. 1, CVR Agreement § 7.10.

59. **The phrase commercially reasonable efforts is not defined in the CVR Agreement.** *See* Ex. 1, CVR Agreement § 1.1.

60. **Sanofi acknowledge these efforts obligations in its public filings, stating that "we have agreed to use diligent efforts, until the CVR agreement is terminated, to achieve each of the Lemtrada related CVR milestones set forth in the CVR agreement. [. . .]"** Ex. 18, Sanofi Form 20-F 2012 ("Sanofi Form 20-F 2012") at 19, available at https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/fr/publications/31972_20-F_2012_V2.pdf (last visited Sept. 11, 2019); *see also* Ex. 302, Sanofi-Aventis, Form F-4 Registration Statement Under the Securities Act of 1933 at 83, 85 (Mar. 7, 2011) (In its SEC Form F-4 in connection with the issuance of the CVRs, Sanofi described the term "Diligent Efforts", and repeated its affirmative efforts obligations to use commercially reasonable efforts to achieve the Production Milestone on a timely basis, and Diligent Efforts to achieve the Approval and Product Sales Milestones.)

61. **Genzyme also acknowledged these obligations in a public filing, stating:**

> **"Following the close of the transaction, [Sanofi] will control the development, production and commercialization of Lemtrada, Cerezyme and Fabrazyme *and will be obligated* to take certain efforts to achieve the Approval Milestone, the Product Sales Milestones and the Production Milestone."**

Ex. 19, Questions and Answers Regarding the CVR, available at https://www.sec.gov/Archives/edgar/data/732485/000095012311017162/b85162exv99waw43.htm (last visited Sept. 11, 2019).

62. **Sanofi has reported €1.583 billion from sales of Lemtrada®.** *See* Ex. 20, Sanofi Form 20-F 2018 ("Sanofi Form 20-F 2018") at 90, available at https://www.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/Home/common/docs/investors/Sanofi-20-F-2018-EN-PDF-e-accessible_01.pdf (Lemtrada sales reached €402 million in 2018 and €474 million in 2017); Ex. 21, Sanofi Form 20-F 2016 ("Sanofi Form 20-F 2016") at 95, 114, available at http://www.annualreports.com/HostedData/AnnualReportArchive/s/NYSE_SNY_2016.pdf (Lemtrada sales reached €425 million in 2016, €243 million in 2015, and €34 million in 2014); Ex. 22, Sanofi Form 20-F 2013 ("Sanofi Form 20-F 2013") at 98, available at https://www.companyreporting.com/sites/default/files/annual-report-index/sanofi-aventis-annual-report-2013.pdf (Lemtrada sales reached €2 million in 2013).

63. **Sanofi has reported €9.4 billion in sales of Cerezyme and Fabrazyme between 2012 and 2018.** *See* Ex. 20, Sanofi Form 20-F 2018 at 90; *see* Ex. 21, Sanofi Form 20-F 2016; *see* Ex. 22, Sanofi Form 20-F 2013 at F-108.

D. Sanofi's Obligations to Bayer Under the CVR Agreement

64. **As part of the merger with Genzyme, Sanofi also assumed Genzyme's obligations under a prior License and Asset Purchase Agreement ("LAPA"), dated March 30, 2009, with Bayer Schering Pharma AG ("Bayer").** *See* Ex. 1, CVR Agreement § 1.1.

65. [redacted]

66. [redacted]

[redacted]

E. Lemtrada® Drug Background

67. **Alemtuzumab is a CD52-directed cytolytic monoclonal antibody approved for the treatment of patients with relapsing forms of multiple sclerosis, and commercialized under the name Lemtrada®.** *See* Ex. 24, Lemtrada Full Prescribing Information at 1 (revised Oct. 2017), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103948s5158lbl.pdf ("Lemtrada Full Prescribing Information").

68. **Lemtrada® is used to treat adults with relapsing multiple sclerosis.** *See* Ex. 24, Lemtrada Full Prescribing Information at 24.

69. **The FDA recommends that the use of Lemtrada® "should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS."** Ex. 24, Lemtrada Full Prescribing Information at 1.

70. **Lemtrada® is administered by intravenous infusion in eight doses of 12mg/day over two years. The first course administers five doses on five consecutive days. 12 months later, 3 doses are administered on three consecutive days.** *See* Ex. 24, Lemtrada Full Prescribing Information at 1.

71. **Lemtrada® patients must be monitored monthly starting after the first infusion for four years or longer after the last round of treatment.** *See* Ex. 24, Lemtrada Full Prescribing Information at 1.

72. **Because of the risks of autoimmunity, infusion reactions, and malignancies, Lemtrada® is only available through a Risk Evaluation and Mitigation Strategy ("REMS") program.** *See* Ex. 24, Lemtrada Full Prescribing Information at 2.

73. [redacted]

74. **Christopher Viehbacher agreed that for certain patients, Lemtrada is "as close to a cure as anyone wants to use the C [cure] word."** Ex. 26, Viehbacher Dep. Tr. at 105:14-105:24.

75. **Sanofi analysts were enthusiastic for Lemtrada®.** *See generally* Ex. 27, SAN-CVR 017566160; Ex. 28, SAN-CVR 016746871.

76. [redacted]

77. [redacted]

78. [redacted]

[redacted]

79. [redacted]

[redacted]

80. **A "blockbuster" drug is a drug that generates annual sales of at least $1 billion.**

See Ex. 26, Viehbacher Dep. Tr. at 273:14-273:22.

81. [redacted]

[redacted]

82. [redacted]

[redacted]

[redacted]

83. [redacted]

[redacted]

84. [redacted]

[redacted]

[redacted]

[redacted]

85. [redacted]

[redacted]

[redacted]

86. [redacted]

[redacted]

87. **Teriflunomide is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis, and commercialized under the name Aubagio®.** *See* Ex. 34, Aubagio Full Prescribing Information at 1 (revised Sept. 2012), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202992s000lbl.pdf ("Aubagio Full Prescribing Information").

88. **Aubagio® is used for the treatment of relapsing forms of multiple sclerosis.** *See* Ex. 34, Aubagio Full Prescribing Information at 1.

89. **Aubagio® is taken orally once daily, in 7 mg or 14 mg doses.** *See* Ex. 34, Aubagio Full Prescribing Information at 1.

90. **Aubagio® was developed by Sanofi prior to the Lemtrada® merger**. *See* Ex. 35, *Teriflunomide, an Inhibitor of Dihydroorotate Dehydrogenase for the Potential Oral Treatment of Multiple Sclerosis*, US NATIONAL LIBRARY OF MEDICINE NATIONAL INSTITUTES OF HEALTH at 1 (Nov. 2010), available at https://www.ncbi.nlm.nih.gov/pubmed/21157651.

F. Sanofi Personnel

91. **Christopher Viehbacher was Sanofi's CEO from September 2008 to October 2014.** *See* Ex. 26, Viehbacher Dep. Tr. at 14:19-14:22; *see* Ex. 36, *Dear Sanofi: Firing CEO Chris Viehbacher Is a Huge Mistake*, FORBES at 1 (Oct. 29, 2014), available at https://www.forbes.com/sites/matthewherper/2014/10/29/dear-sanofi-firing-ceo-chris-viehbacher-is-a-huge-mistake/#4617521b75c0.

92. **Christopher Viehbacher was the CEO of Sanofi at the time of the merger.** *See* Ex. 26, Viehbacher Dep. Tr. at 14:19-14:22.

93. [redacted]

94. [redacted]

95. [redacted]

96. **Olivier Brandicourt became Sanofi's CEO on April 2, 2015.** *See* Ex. 25, Brandicourt Dep. Tr. at 6:21-6:23.

97. **Jerome Contamine was CFO of Sanofi from 2009 to 2018.** *See* Ex. 38, *Sanofi's CFO Contamine to Retire Later this Year*, REUTERS at 1 (Apr. 17, 2018), available at https://www.reuters.com/article/us-sanofi-management/sanofis-cfo-contamine-to-retire-later-this-year-idUSKBN1HO2YQ.

98. **Jerome Contamine announced his retirement as CFO of Sanofi in April 2018.** *See* Ex. 38, *Sanofi's CFO Contamine to Retire Later this Year*, REUTERS at 1 (Apr. 17, 2018), available at https://www.reuters.com/article/us-sanofi-management/sanofis-cfo-contamine-to-retire-later-this-year-idUSKBN1HO2YQ.

99. **Elias Zerhouni was Sanofi's "President of Research and Development" ("R&D") from 2011 to 2018.** Ex. 39, November 7, 2018 Videotaped Deposition of Elias Zerhouni ("Zerhouni Dep. Tr.") at 7:7-7:12; 304:20-304:21.

100. **Elias Zerhouni announced his retirement as Global Head of R&D in April 2018.** *See* Ex. 40, *John Reed to Replace Zerhouni as Sanofi Head of Global R&D*, REUTERS at 1

(April 24, 2018), available at https://www.reuters.com/article/brief-john-reed-to-replace-zerhouni-as-s/brief-john-reed-to-replace-zerhouni-as-sanofi-head-of-global-rd-idUSFWN1S106D.

101. **David Meeker was CEO of Genzyme from November 2011 to June 2017.** *See* Ex. 41, *Sanofi Appoints David Meeker Chief Executive Officer of Genzyme*, SANOFI GENZYME WEBSITE at 1 (Oct. 24. 2011), available at https://news.genzyme.com/press-release/sanofi-appoints-david-meeker-chief-executive-officer-genzyme; Ex. 42, July 26, 2018 Videotaped Deposition of David Meeker ("Meeker Dep. Tr.") at 115:10-115:12.

[redacted]

103. **Bill Sibold is the Head of the Multiple Sclerosis franchise at Sanofi.** *See* Ex. 44, *Bill Sibold, Executive Vice President and Head of Sanofi Genzyme*, SANOFI GENZYME WEBSITE at 1, available at https://www.sanofigenzyme.com/en/about-us/our-leadership/bill-sibold (last visited Aug. 28, 2019).

104. **Since July 2017, Bill Sibold is Head of Sanofi Genzyme.** *See* Ex. 45, *Bill Sibold,* LINKEDIN at 2, available at https://www.linkedin.com/in/bill-sibold-4a2a628/ (last visited Aug. 29, 2019).

105. **Mark Underwood was VP of Global Commercial Strategy for Multiple Sclerosis from 2014 to 2016.** *See* Ex. 46, July 31, 2018 Videotaped Deposition of Mark Underwood ("Underwood Dep. Tr.") at 10:6-10:24; *see* Ex. 47, *Mark Underwood*, LINKEDIN at 1, available at https://www.linkedin.com/in/mark-underwood-58bb8230/ (last visited Aug. 2, 2019).

106. **Mark Underwood was Global Head of New Product Planning for MS, Oncology and Immunology from 2016 to 2018.** *See* Ex. 47, *Mark Underwood*, LINKEDIN at 1, available at https://www.linkedin.com/in/mark-underwood-58bb8230/ (last visited Aug. 2, 2019).

107. **Stephen Lake was Head of Genzyme Biostatistics from 2012 to 2015.** *See* Ex. 48, *Stephen Lake*, LINKEDIN at 2, available at https://www.linkedin.com/in/stephen-lake-524b5121/ (last visited Aug. 2, 2019).

108. **Stephen Lake was the lead statistician on Sanofi's Lemtrada® application to the FDA.** *See* Ex. 49, November 16, 2017 Videotaped Deposition of Stephen Lake ("Lake Dep. Tr.") at 11:4-11:18.

109. **Michael Panzara was Head of Global Development for MS, Neurology, and Ophthalmology at Sanofi Genzyme.** *See* Ex. 50, *Michael Panzara*, LINKEDIN at 2, available at https://www.linkedin.com/in/michael-panzara-3981542b/ (last visited Aug. 2, 2019).

110. **Michael Panzara oversaw FDA approval process for Lemtrada®.** *See* Ex. 51, October 24, 2017 Videotaped Deposition of Michael Panzara ("Panzara Dep. Tr.") at 14:6-14:12.

111. **Jennifer Panagoulias was in Regulatory Affairs at Sanofi Genzyme from 1998 to 2015.** *See* Ex. 52, November 1, 2017 Videotaped Deposition of Jennifer Panagoulias ("Panagoulias Dep. Tr.") at 10:22-12:4.

112. **Jennifer Panagoulias headed the regulatory affairs strategy for Lemtrada®.** *See* Ex. 52, Panagoulias Dep. Tr. at 24:14-25:4.

113. **Tom Snow was VP of the Multiple Sclerosis Business Unit in Europe from August 2014 to September 2017.** *See* Ex. 53, *Tom Snow*, LINKEDIN, available at https://www.linkedin.com/in/tom-snow-3803482/ (last visited Aug. 2, 2019).

114. **Since October 2017, Tom Snow is the Global Multiple Sclerosis Franchise Head at Sanofi Genzyme.** *See* Ex. 53, *Tom Snow*, LINKEDIN, available at https://www.linkedin.com/in/tom-snow-3803482/ (last visited Aug. 2, 2019).

115. **Carole Huntsman was Head of the Multiple Sclerosis Business Unit for North America from January 2012 to December 2015.** *See* Ex. 54, *Carole Huntsman*, LINKEDIN, available at https://www.linkedin.com/in/carole-huntsman-2a984b1/ (last visited Aug. 3, 2019).

116. **Carole Huntsman was Global Multiple Sclerosis Lead from January 2016 to May 2017.** *See* Ex. 54, *Carole Huntsman*, LINKEDIN, available at https://www.linkedin.com/in/carole-huntsman-2a984b1/ (last visited Aug. 3, 2019).

117. **Since May 2017, Carole Huntsman is the Head of Multiple Sclerosis, Oncology and Immunology for North America.** *See* Ex. 54, *Carole Huntsman*, LINKEDIN, available at https://www.linkedin.com/in/carole-huntsman-2a984b1/ (last visited Aug. 3, 2019).

II. Sanofi Executives Ignored or Were Not Aware of Their Obligations Under the CVR Agreement

118. **Christopher Viehbacher, as Sanofi CEO, negotiated the merger and aspects of the CVR Agreement.** *See* Ex. 26, Viehbacher Dep. Tr. at 47:13-47:16.

119. **Christopher Viehbacher had "some involvement with" the negotiation of the Diligent Efforts provision of the CVR Agreement.** Ex. 26, Viehbacher Dep. Tr. at 114:21-114:24.

120. **Christopher Viehbacher could not recall if he read the CVR Agreement cover to cover.** *See* Ex. 26, Viehbacher Dep. Tr. at 49:11-49:24.

121. **Christopher Viehbacher never issued any written instructions with respect to the CVR.** *See* Ex. 26, Viehbacher Dep. Tr. at 129:6-131:14.

122. **Christopher Viehbacher testified that the CVR agreement did not give Sanofi "an extra sense of urgency."** *See* Ex. 26, Viehbacher Dep. Tr. at 136:17-136:19.

123. **Serge Weinberg testified that he never read the CVR Agreement or any summary thereof.** *See* Ex. 37, Weinberg Dep. Tr. at 15:12-15:23; 119:17-119:20.

124. **Serge Weinberg was "not informed" that the CVR Agreement "required Sanofi to use Diligent Efforts to achieve the approval milestone and the four product [sales] milestones."** Ex. 37, Weinberg Dep. Tr. at 18:10-18:15; 119:17-119:20.

125. **Serge Weinberg testified that the CVR Agreement did not "create any special attention at the board level."** Ex. 37, Weinberg Dep. Tr. at 47:11-47:15.

126. **Serge Weinberg did not task anyone with overseeing compliance with the CVR Agreement.** *See* Ex. 37, Weinberg Dep. Tr. at 23:6-23:25.

127. **Serge Weinberg testified that no exceptions were made for Lemtrada in budget discussions.** *See* Ex. 37, Weinberg Dep. Tr. at 84:25-85:13.

128. **Olivier Brandicourt testified that he never read the CVR Agreement or any summary thereof and did not have a copy of it.** *See* Ex. 25, Brandicourt Dep. Tr. at 15:5-15:24.

129. [redacted]

130. [redacted]

131. **Jerome Contamine testified that he does "not know the details" of the CVR Agreement.** *See* Ex. 55, September 5, 2018 Videotaped Deposition of Jerome Contamine ("Contamine Dep. Tr.") at 292:19-292:21.

132. **Elias Zerhouni testified that he was not provided with a copy of the CVR Agreement when he joined Sanofi or any specific instructions as to Sanofi's obligations under the CVR Agreement.** *See* Ex. 39, Zerhouni Dep. Tr. at 56:11-56:23.

133. **Elias Zerhouni testified that allocation of resources to Lemtrada® involved the "same extent of diligence and effort" as other products and that the CVR Agreement did not require additional efforts.** *See* Ex. 39, Zerhouni Dep. Tr. at 56:24-57:7.

134. **David Meeker testified that he could not recall if he had ever seen the CVR Agreement in its entirety and was never informed "of the terms of that CVR."** *See* Ex. 42, Meeker Dep. Tr. at 10:12-12:7.

135. [redacted]

136. **Bill Sibold testified that he could not remember if he was given any instructions on what the CVR Agreement meant.** *See* Ex. 56, July 17, 2018 Videotaped Deposition of William J. Sibold ("Sibold Dep. Tr.") at 17:17-17:19.

137. **Bill Sibold testified that he never discussed the CVR Agreement with others at Sanofi.** *See* Ex. 56, Sibold Dep. Tr. at 18:2-18:14.

138. **Mark Underwood testified that he was not explicitly aware that Sanofi was under a contractual obligation to use diligent efforts to achieve certain milestones.** *See* Ex. 46, Underwood Dep. Tr. at 200:8-200:23.

139. **Stephen Lake testified that he had no discussions with anyone at Sanofi concerning the CVR Agreement.** *See* Ex. 49, Lake Dep. Tr. at 16:12-16:15.

140. **Michael Panzara testified that his superiors did not instruct him as to what was required of him to comply with the CVR Agreement.** *See* Ex. 51, Panzara Dep. Tr. at 18:14-21:13.

141. **Tom Snow testified that he had never seen the CVR Agreement.** *See* Ex. 57, June 22, 2018 Videotaped Deposition of Thomas Snow ("Snow Dep. Tr.") at 9:15-11:3.

142. **Tom Snow also testified that he had never heard of Sanofi's Diligent Efforts obligations.** *See* Ex. 57, Snow Dep. Tr. at 9:15-11:3.

143. **Carole Huntsman testified that she never read the CVR Agreement, was never given a summary of the CVR Agreement, and never had any discussions about it.** *See* Ex. 58, May 8, 2018 Videotaped Deposition of Carole Huntsman ("Huntsman Dep. Tr.") at 254:25-256:7.

144. **Carole Huntsman also testified that she heard of the CVR Agreement reading about it in the news.** *See* Ex. 58, Huntsman Dep. Tr. at 254:25-255:14.

III. Sanofi Calculated Lemtrada®'s Profitability by Including Both the Bayer Royalty and CVR Milestone Payments and Considered These Calculations when Cutting Lemtrada®'s Budget.

145. **PSM#1 is triggered when Lemtrada® sales in a defined period hit $400 million.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone #1", "Product Sales Milestone Payment."

146. **As of December 31, 2016, there were 236,457,284 CVRs outstanding.** *See* Ex. 59, Plaintiff UMB Bank, N.A., as Trustee's Responses and Objections to Defendant's First Set of Requests for Admission at 21.

147. **Given the number of CVRs outstanding, the associated payment of $2 per CVR would amount to more than the $400 million sales amount**. *See* Ex. 1, CVR Agreement § 1.1, definition of "Product Sales Milestone Payment"; *see* Ex. 17, SAN-CVR 013574104 at 104.

148. [redacted]

149. **The Diligent Efforts obligation in the CVR Agreement allows Sanofi to consider the profitability of Lemtrada® in exercising its Diligent Efforts to achieve the milestones, but *only* "consistent with the Company's publicly reported financial statements."** Ex. 1, CVR Agreement § 1.1, definition of "Diligent Efforts."

150. **Business Operating Income ("BOI") is the standard metric Sanofi uses to track and report profitability of its products**. *See* Ex. 43, Esteva Dep. Tr. at 28:10-28:23; *see* Ex. 22, Sanofi Form 20-F 2013 at 84 ("For our business segments, we also measure our results of operations through an indicator referred to as 'Business Operating Income.'" "'Business Operating Income' is derived from 'Operating income', adjusted as follows:

- the amounts reported in the line items 'Fair value remeasurement of contingent consideration liabilities', 'Restructuring costs' and 'Other gains and losses, and litigation' are eliminated;
- amortization and impairment losses charged against intangible assets (other than software) are eliminated;
- the share of profits/losses of associates and joint ventures is added;
- the share attributable to non-controlling interests is deducted;
- other acquisition-related effects (primarily, the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated; and
- restructuring costs relating to associates and joint ventures are eliminated.").

151. [redacted]

152. **The Diligent Efforts obligation does not allow Sanofi to consider the CVR milestone payments and 35% Bayer Royalties when analyzing Lemtrada® profitability.** *See* Ex. 1, CVR Agreement § 1.1, definition of "Diligent Efforts" (Sanofi is allowed to consider the profitability of Lemtrada "consistent with the Company's publicly reported financial statements (assuming the Company will not treat royalty payments to BSP as an expense for purposes of this clause, or the achievement of Milestones in such a manner, that would reduce the profitability of the Product)").

153. **Before the merger, Sanofi prepared financial modeling of the CVR payments and assessed likelihood of CVR payments.** *See* Ex. 60, Evercore-UMB 00015174 at 177; Ex. 8, Genzyme 14D-9 at 42.

154. [redacted]

156. **Christopher Viehbacher testified that Sanofi re-purchased CVRs because it was Sanofi's "view that the CVR value as traded on the stock exchange was lower than our expected net present value of what we thought the CVR was worth. So we decided to buy up CVRs at what we deemed to be a lower price than what they were worth. That would have**

indicated that we had a higher expectation of Lemtrada sales than the market." Ex. 26, Viehbacher Dep. Tr. at 79:11-79-18.

157. [redacted]

158. [redacted]

159. [redacted]

160. [redacted]

A. <u>After the Merger, Sanofi Imposed Budget Cuts Rather than Invest in Developing Lemtrada®'s Market Potential</u>

161. **In the year following Sanofi's acquisition of Genzyme, Sanofi mandated budget cuts across the organization.** *See* Ex. 64, SAN-CVR 020065419 at 422; *see* Ex. 26, Viehbacher Dep. Tr. at 235:7-235:25 ("[t]his is in March of 2011, so it's just immediately after the announcement of the Genzyme deal, at which we had promised, I believe, $700 million of cost

synergies to come out of the – out of the company."); *see* Ex. 39, Zerhouni Dep. Tr. at 40:2-41:8 ("So when you looked at the long-range strategic plan for R&D as you mentioned, the goal was to keep the total envelope flat or slightly declining, not just R&D. R&D, medical affairs, regulatory, all of it.").

162. **Allocations in the budget were "defined Jerome [Contamine] and Chris [Viehbacher]".** *See* Ex. 39, Zerhouni Dep. Tr. at 114:19-115:10.

163. **No exception on budget cuts was made for Lemtrada®, despite the Diligent Efforts obligations**. *See* Ex. 25, Brandicourt Dep. Tr. at 80:11-81:4 ("Q: And is it your testimony that you cannot recall ever giving a moment's thought to the CVR agreement in any of your budget challenges? A: That didn't come up."); *see* Ex. 37, Weinberg Dep. Tr. at 84:25-85:13 (Serge Weinberg testified that no exceptions were made for Lemtrada in budget discussions); *see, e.g.*,

[redacted]

164. [redacted]

165. [redacted]

166. [redacted]

167. [redacted]

168. [redacted]

169. [redacted]

170. [redacted]

171. [redacted]

172. [redacted]

173. [redacted]

B. [redacted]

174. [redacted]

175. [redacted]

176. [redacted]

177. [redacted]

178. [redacted]

179. [redacted]

180. [redacted]

181. [redacted]

182. [redacted]

183. [redacted]

184. [redacted]

185. **David Meeker testified that "Lemtrada was the only [Sanofi] product" that has these additional (below the line) calculations from BOI to free cash flow "to understand the profitability of the product."** *See* Ex. 42, Meeker Dep. Tr. at 43:2-43:22.

186. [redacted]

187. [redacted]

188. [redacted]

189. [redacted]

190. [redacted]

191. [redacted]

192. [redacted]

a. [redacted]

194. [redacted]

195. [redacted]

196. [redacted]

197. [redacted]

198. [redacted]

199. [redacted]

200. [redacted]

201. [redacted]

202. [redacted]

203. [redacted]

204. [redacted]

205. [redacted]

206. [redacted]

207. [redacted]

208. [redacted]

209. [redacted]

210. [redacted]

211. [redacted]

212. [redacted]

213. [redacted]

214. [redacted]

215. [redacted]

216. [redacted]

217. [redacted]

218. [redacted]

219. [redacted]

220. [redacted]

C. Sanofi Continued to Cut the Budget for Lemtrada® in 2013 and 2014

221. [redacted]

222. [redacted]

223. [redacted]

224. [redacted]

[redacted]

225. [redacted]

226. [redacted]

227. [redacted]

228. [redacted]

229. [redacted]

230. [redacted]

231. [redacted]

232. [redacted]

233. [redacted]

234. [redacted]

235. [redacted]

236. [redacted]

237. [redacted]

[redacted]

238. [redacted]

239. [redacted]

IV. Sanofi Rejected or Blocked Investments Previously Planned by Genzyme for the Development of Lemtrada®

A. Life Cycle Management Is a Well-Accepted Aspect of the Pharmaceutical Business, Required to Build and Maintain a Profitable Product

240. **Life cycle management ("LCM") is the process of creating a plan to ensure the long-term success of a product, including generation of new data, new formulations, and new indications.** *See* Ex. 56, Sibold Dep. Tr. at 68:15-68:25.

241. **LCM can require the generation of evidence through additional studies.** *See* Ex. 114, SAN-CVR 011222957 at 957; *see also* Ex. 115, May 3, 2018 Videotaped Deposition of Pamela Williamson ("Williamson Dep. Tr.") at 271:15-271:23.

242. **LCM is vital to the success of pharmaceutical products.** *See* Ex. 114, SAN-CVR 011222957 at 957; Ex. 115, Williamson Dep. Tr. at 271:15-271:23.

243. **LCM is a typical practice for "prudent pharmaceutical companies."** Ex. 58, Huntsman Dep. Tr. at 35:8-35:11; Ex. 115, Williamson Dep. Tr. at 271:24-272:11.

244. **LCM can include studies to expand the label of a drug.** Ex. 58, Huntsman Dep. Tr. at 34:12-34:19.

245. **LCM can include reformulations of a drug.** Ex. 58, Huntsman Dep. Tr. at 35:12-35:16.

246. [redacted]

247. [redacted]

248. [redacted]

249. [redacted]

250. [redacted]

251. [redacted]

B. Life Cycle Management Requires Investment to Capture Market Potential for a Drug

252. [redacted]

253. [redacted]

254. [redacted]

255. [redacted]

C. PPMS is a Subset of MS Which Was a Promising Treatment Segment for Lemtrada®, but [redacted]

256. [redacted]

257. **PPMS is a form of multiple sclerosis characterized by worsening neurologic function (accumulation of disability) from the onset of symptoms, without early relapses or remissions.** *See* Ex. 122, *Primary Progressive MS (PPMS)*, NATIONAL MULTIPLE SCLEROSIS SOCIETY at 1, available at https://www.nationalmssociety.org/What-is-MS/Types-of-MS/Primary-progressive-MS (last visited Aug. 29, 2019).

258. [redacted]

259. **PPMS is an unmet need in multiple sclerosis.** *See* Ex. 58, Huntsman Dep. Tr. at 198:22-199:3.

260. **An unmet need is a condition whose treatment or diagnoses is not addressed adequately by available therapy.** *See* Ex. 56, Sibold Dep. Tr. at 75:15-75:22.

261. [redacted]

262. [redacted]

[redacted]

263. [redacted]

264. [redacted]

265. **Even though Sanofi thought Lemtrada® was a potential blockbuster, Sanofi did not fund any formulation of these studies in 2012 and 2013.** *See* [redacted]; *see also* Ex. 46, Underwood Dep. Tr. 281:15-282:14 (Regarding the Phase II progressive MS subQ study, "[t]he proposal from the team was to not fund it for 2013."); *see also* [redacted]

266. [redacted]

267. [redacted]

268. **As of December 2017, Bill Sibold believed that "it would merit running a study to find out whether […] alemtuzumab had the potential to meet the high umet need in PPMS."** Ex. 56, Sibold Dep. Tr. at 77:12-77:22.

269. **Ocrevus®, the first FDA approved drug for PPMS, was launched by Roche on March 28, 2017.** *See* Ex. 131, *FDA Approves New Drug to Treat Multiple Sclerosis*, U.S. FOOD & DRUG ADMINISTRATION at 1 (Mar. 29, 2017), available at https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treat-multiple-sclerosis.

270. [redacted]

271. [redacted]

272. **Ocrevus® was not available from November 2014 through March 2017.** *See* Ex. 131, *FDA Approves New Drug to Treat Multiple Sclerosis*, U.S. FOOD & DRUG ADMINISTRATION at 1 (Mar. 29, 2017), available at https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treat-multiple-sclerosis.

273. **In its first full year after its mid-2017 launch, Ocrevus® achieved blockbuster status with $2.4 billion in 2018 sales. In the first quarter of 2019 alone, Ocrevus® brought in $829 million in global sales.** *See* Ex. 132, *Roche's Ocrevus Continues Winning Streak as NICE Flip-Flops on Initial Rejection*, FIERCEPHARMA at 1-2 (May 9, 2019), available at

https://www.fiercepharma.com/pharma/roche-genentech-s-ocrevus-continues-winning-streak-after-nice-flip-flops-initial-guidance.

D. [redacted]

274. [redacted]

275. [redacted]

276. [redacted]

277. [redacted]

278. [redacted]

279. [redacted]

E. [redacted]

280. [redacted]

281. [redacted]

282. [redacted]

283. [redacted]

284. [redacted]

285. **Pamela Williamson, one of Sanofi's regulatory affairs professionals, agreed that allocating resources to a biomarker study "is part of what a reasonable pharmaceutical company does."** Ex. 115, Williamson Dep. Tr. at 159:22-160:9.

286. [redacted]

287. [redacted]

F. [redacted]

288. **"Durable disability improvement" is a potential unmet need in multiple sclerosis.** Ex. 58, Huntsman Dep. Tr. at 144:4-144:11; Ex. 138, SAN-CVR 016660131 at 136.

289. [redacted]

290. **Lemtrada® had the potential to delay the accrual of disability, improve disability, and even reverse disability in MS patients and can fundamentally improve their lives.** *See* Ex. 49, Lake Dep. Tr. at 261:6-262:24; [redacted] Ex. 42, Meeker Dep. Tr. at 92:16-92:25 ("Q: […] Lemtrada, in that cohort of patients, slowed the accumulation of disability in patients, correct? A. Yes. Q. And that is referred to sometimes as an improvement in disability? A. It can accommodate, in that definition, an improvement.").

291. [redacted]

292. [redacted]

293. [redacted]

V. Sanofi Made Multiple Errors in Seeking FDA Approval for Lemtrada®, Causing Them to Receive Both a Refuse to File and Complete Response Letter from the FDA and Miss the Approval Milestone

294. **The FDA will approve a new drug or biologic if it finds that a sponsor has performed drug trials that provide statistical proof that the product is safe and effective.** *See* Ex. 141, *Development & Approval Process (Drugs)* at 1-2, U.S. FOOD & DRUG ADMINISTRATION (last updated June 13, 2018), available at https://www.fda.gov/drugs/developmentapprovalprocess/default.htm.

295. **Drug trials are subject to bias, which can skew a trial's results and suggest a product is safe and effective when it is not.** *See* Ex. 49, Lake Dep. Tr. at 23:6-23:12; 33:14-33:22.

296. **Where a study introduces a potential bias, the FDA will look to the sponsor to rule out that bias** [redacted] *See* Ex. 115, Williamson Dep. Tr. at 43:9-43:12; [redacted]

297. [redacted]

A. **Phase III Clinical Trials for Lemtrada® Produced [redacted] Results, After Which Sanofi Prepared to Submit Its Application to the FDA for Approval of Lemtrada in MS**

298. [redacted]

299. [redacted]

300. **In an "open-label, rater-blind" study, both the subjects and the researchers know which treatment a subject receives ("open-label"), but a "rater" who does not know which treatment the subject received ("rater-blinded") analyzes certain conditions reported by the subject.** *See* Ex. 145, *Open Label Study*, NATIONAL CANCER INSTITUTE at 1, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/open-label-study (last visited Sept. 3, 2019); *see* Ex. 146, *Blind Study*, MEDICAL DICTIONARY at 1, available at https://medical-dictionary.thefreedictionary.com/blind+study (last visited Sept. 3, 2019).

301. **A "double-blind" study is a study in which neither the subjects nor the researchers know which treatment—either the drug under study or a comparator drug or placebo—a subject receives.** Ex. 49, Lake Dep. Tr. at 36:21-37:15.

302. [redacted]

303. **The Expanded Disability Status Scale ("EDSS") is a method of quantifying disability in multiple sclerosis** [redacted]

[redacted] *see* Ex. 51, Panzara Dep. Tr. at 37:5-37:14; [redacted]

304. **The EDSS score is a subjective measurement used to assess the health of a patient with multiple sclerosis.** *See* Ex. 52, Panagoulias Dep. Tr. at 164:2-164:4.

305. **A screening EDSS score is taken when determining whether a patient will participate in the study but before she is assigned the drug she is being treated with. A baseline EDSS score is taken after the patient knows what drug she is receiving.** *See* Ex. 49, Lake Dep. Tr. at 44:20-44:23; 138:7-138:10.

306. [redacted]

307. [redacted]

B. <u>Sanofi Submitted Its Application to the FDA for Lemtrada® but It Was Rejected Due to Biostatistics Concerns</u>

308. **To obtain a license to introduce a biological product for a new use into interstate commerce in the United States, an entity must submit a biologics license application ("BLA") to the FDA.** *See* Ex. 149, 21 C.F.R. § 601.20.

309. **If the FDA has already approved a biosimilar product for a different use, then the entity seeking approval must submit a supplemental biologics license application ("sBLA").** *See* Ex. 150, 21 C.F.R. § 601.12.

310. [redacted]

311. **A BLA or sBLA must present specific information, data, and analyses related to the drug.** *See generally* Ex. 149, 21 C.F.R. § 601.20; *see also* Ex. 150, 21 C.F.R. § 601.12.

312. **A BLA or sBLA must, among other things, present substantial evidence of a drug's efficacy by demonstrating that the clinical trials were "adequate and well-controlled."** *See* Ex. 152, 21 C.F.R. § 314.126.

313. [redacted]

314. [redacted]

315. [redacted]

316. [redacted]

317. [redacted]

318. [redacted]

319. [redacted]

321. [redacted]

[redacted]

322. [redacted]

323. [redacted]

324. [redacted]

325. [redacted]

326. [redacted]

327. [redacted]

328. [redacted]

329. [redacted]

C. [redacted]

331. **On December 30, 2013, Sanofi and Genzyme announced that Genzyme "plans to appeal the agency's decision."** Ex. 162, *Genzyme Receives Complete Response Letter from FDA on Lemtrada (alemtuzumab) Application*, SANOFI GENZYME WEBSITE at 2 (Dec. 30, 2013), available at https://www.sanofigenzyme.com/en/about-us/newsroom/archive/2013/2013-12-30-01-02-00.

332. **On March 31, 2014, the deadline for the Approval Milestone passed.** *See* Ex. 1, CVR Agreement § 1.1 at 2.

333. [redacted]

334. [redacted]

335. [redacted]

336. [redacted]

337. **The FDA approved Lemtrada® on November 14, 2014, approximately seven months after the deadline for the Approval Milestone.** *See* Ex. 165, *Genzyme's Lemtrada Approved by the FDA*, SANOFI GENZYME WEBSITE at 1 (Nov. 14, 2014), available at https://news.genzyme.com/press-release/genzymes-lemtrada-approved-fda.

D. [redacted]

338. [redacted]

339. [redacted]

340. [redacted]

341. **In 2005, FDA statistical reviewer Dr. Sharon Yan, expressed concern regarding variability between the screening and baseline EDSS scores in the approval of another multiple sclerosis drug, Tysabri®. Dr. Yan noted that "[t]he fluctuation of EDSS Score between screening visit and baseline visit raises the concern of the interpretation of the results, since the primary efficacy endpoint of time to disability progression is based on changes in EDSS from baseline" and that certain patients in each arm of the trial would not have met EDSS progression criteria had the screening EDSS been used in lieu of baseline whereas others might have met the criteria had there been no change.** Ex. 168, Statistical Review and Evaluation, Clinical Studies, *sBLA of Natalizumab*, at 4-5 (2005), available at https://wayback.archive-it.org/7993/20170405065340/https://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4208B1_01_05FDAStatistical%20review.pdf.

342. [redacted]

343. [redacted]

344. **Multiple sclerosis literature also recognized that EDSS variability between screening and baseline could impact treatment results.** *See generally* Ex. 172, Jiameng Zhang;

Emmanuelle Waubant; Gary Cutter; Jerry S. Wolinsky; and Robert Glanzman, *EDSS variability before randomization may limit treatment discovery in primary progressive MS*, MULTIPLE SCLEROSIS JOURNAL (Date Received: Apr. 24, 2012); *see also* Ex. 173, SAN-CVR 012646972 at 972.

345. [redacted]

346. [redacted]

347. [redacted]

348. [redacted]

349. [redacted]

350. [redacted]

351. [redacted]

352. [redacted]

353. [redacted]

354. [redacted]

[redacted]

355. [redacted]

[redacted]

***

[redacted]

356. [redacted]

a. [redacted]

b. [redacted]

357. [redacted]

358. [redacted]

359. [redacted]

360. [redacted]

361. **Lemtrada® was approved 29 months after submission of the sBLA in June 2012.** *See* Ex. 165, *Genzyme's Lemtrada Approved by the FDA*, SANOFI GENZYME WEBSITE at 1 (Nov. 14, 2014), available at https://news.genzyme.com/press-release/genzymes-lemtrada-approved-fda.

362. [redacted]

E. [redacted]

363. [redacted]

364. [redacted]

365. [redacted]

366. [redacted]

367. [redacted]

a. [redacted]

368. [redacted]

369. [redacted]

370. [redacted]

371. [redacted]

372. [redacted]

373. [redacted]

VI. The Commercialization and Launch of Lemtrada® Showed a Lack of Diligent Efforts and, in Fact, Showed a Concerted Desire to Avoid Product Sales Milestone #1

374. **The launch of Lemtrada® in North America was orchestrated by Carole Huntsman, who was responsible for building Sanofi's MS franchise and preparing the launches of Aubagio® and Lemtrada® in North America.** *See* Ex. 58, Huntsman Dep. Tr. at 80:24-81:5.

375. **Mark Underwood was Sanofi's Vice President of Global Commercial Strategy for multiple sclerosis during the relevant time period.** *See* Ex. 46, Underwood Dep. Tr. at 9:7-9:11.

376. **Bill Sibold was head of MS during the time period relevant to PSM#1.** *See* Ex. 56, Sibold Dep. Tr. at 185:8-185:21.

377. **Bill Sibold testified that the approach Sanofi took to the launch of Lemtrada® "was not to look to achieve milestones. It was to maximize the value of the product."** Ex. 56, Sibold Dep. Tr. at 21:15-21:19.

A. [redacted]

378. **The responsibility for ensuring a successful Lemtrada® launch in Europe rested with Tom Snow, then European commercial lead for MS.** *See* Ex. 57, Snow Dep. Tr. at 8:4-8:18.

379. [redacted]

380. [redacted]

381. [redacted]

382. **Determining an appropriate price for Lemtrada® required determining a price that would be consistent with Lemtrada®'s product profile, and that would also allow**

Sanofi to promptly seek pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets. *See* Ex. 1, CVR Agreement § 1.1, definition of "Diligent Efforts."

383. [redacted]

384. [redacted]

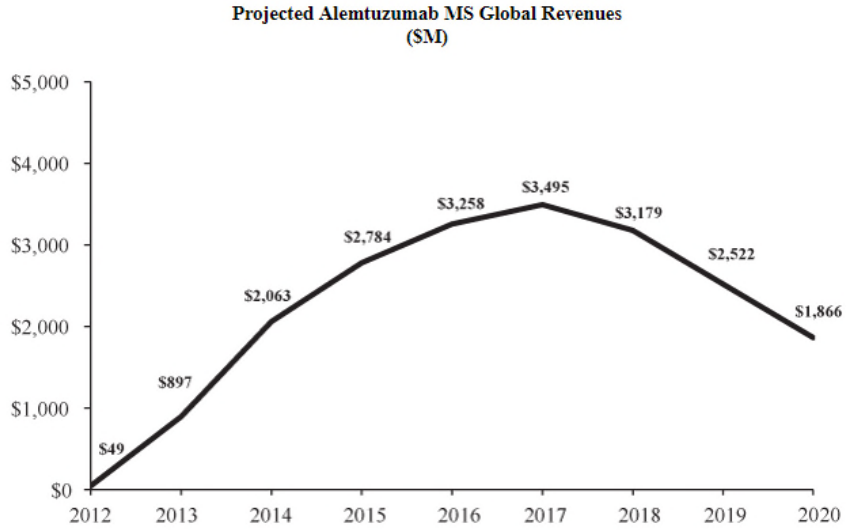
385. [redacted]

386. [redacted]

387. [redacted]

388. [redacted]

389. **This approach is consistent with the projections for Lemtrada®'s global sales sent to Genzyme's shareholders seeking approval of the merger, which demonstrated that peak revenues for Lemtrada® were to occur within the first five years of launch**:



Ex. 8, Genzyme Schedule 14D-9 at 14.

390. [redacted]

[redacted]

391. [redacted]

[redacted]

392. [redacted]

[redacted]

393. [redacted]

[redacted]

394. [redacted]

[redacted]

395. [redacted]

[redacted]

396. [redacted]

[redacted]

397. [redacted]

[redacted]

398. [redacted]

399. [redacted]

400. [redacted]

401. [redacted]

402. **To this date, Lemtrada® has yet to launch in France.** *See* Ex. 195, SAN-CVR 015018016; Ex. 196, *Alemtuzumab*, COMMISSION DE LA TRANSPARENCE at 2 (Oct. 3, 2018), available at https://www.has-sante.fr/upload/docs/evamed/CT-16924_LEMTRADA_PICr%C3%A9%C3%A9val_avis3_CT16924%20(2).pdf (The National Authority for Health (Haute Autorité de Santé) assessed Lemtrada® and assigned an ASMR V, stating that Lemtrada does not offer additional benefit versus current treatment options.)

B. [redacted]

403. [redacted]

404. [redacted]

405. [redacted]

406. [redacted]

407. [redacted]

408. [redacted]

C. [redacted]

409. [redacted]

410. [redacted]

411. [redacted]

412. [redacted]

413. [redacted]

414. [redacted]

415. [redacted]

416. [redacted]

417. [redacted]

418. [redacted]

419. [redacted]

420. [redacted]

[redacted]

421. [redacted]

422. [redacted]

423. [redacted]

424. [redacted]

D. [redacted]

425. [redacted]

426. [redacted]

427. [redacted]

428. [redacted]

429. [redacted]

430. [redacted]

431. [redacted]

432. [redacted]

433. [redacted]

434. [redacted]

435. [redacted]

436. [redacted]

[redacted]

437. [redacted]

438. [redacted]

439. [redacted]

440. [redacted]

441. [redacted]

442. [redacted]

[redacted]

443. [redacted]

444. [redacted]

445. [redacted]

446. [redacted]

E. [redacted]

447. [redacted]

448. [redacted]

449. [redacted]

451. **The targeted launch of Lemtrada® in the United States began after FDA approval was obtained on November 14, 2014.** *See* Ex. 165, *Genzyme's Lemtrada Approved by the FDA*, SANOFI GENZYME WEBSITE at 1 (Nov. 14, 2014), available at https://news.genzyme.com/press-release/genzymes-lemtrada-approved-fda; *see generally*, Ex. 215, SAN-CVR 020086802.

452. [redacted]

453. [redacted]

454. [redacted]

[redacted]

456. **According to Christopher Viehbacher, launching in December would not produce high sales.** Ex. 26, Viehbacher Dep. Tr. at 164:13-165:24.

457. **Christopher Viehbacher testified that "if you launched in December and there's not many physicians to go see, then, you know, you'd actually start in January . . . ."** Ex. 26, Viehbacher Dep. Tr. at 164:13-165:24.

F. [redacted]

458. [redacted]

459. [redacted]

460. [redacted]

[redacted]

461. [redacted]

[redacted]

462. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

[redacted]

463. [redacted]

[redacted]

465. [redacted]

466. [redacted]

467. [redacted]

469. [redacted]

470. [redacted]

471. [redacted]

472. [redacted]

473. [redacted]

[redacted]

474. [redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

475. [redacted]

476. [redacted]

477. [redacted]

478. [redacted]

479. [redacted]

G. [redacted]

480. [redacted]

481. [redacted]

482. [redacted]

483. [redacted]

484. [redacted]

485. **In an interview with a pharmaceutical marketing news outlet, Carole Huntsman acknowledged that in contrast with the Lemtrada staff, the Aubagio® team came together "really quickly" before the product's FDA approval.** Ex. 254, Carly Helfand, *The Bright Side to Sanofi's Lemtrada Delay? Its Support-to-Sell Marketing Plan*, FIERCEPHARMA at 1 (Dec. 23, 2014), available at https://www.fiercepharma.com/sales-and-marketing/bright-side-to-sanofi-s-lemtrada-delay-its-support-to-sell-marketing-plan.

486. [redacted]

488. [redacted]

489. [redacted]

H. [redacted]

490. [redacted]

491. [redacted]

492. [redacted]

493. [redacted]

494. [redacted]

495. [redacted]

[redacted]

496. [redacted]

497. [redacted]

498. [redacted]

499. **With respect to PSM#1, if sales of Lemtrada® reached $400 million in sales in the relevant time period, Sanofi would be required to pay the CVR holders over $586 million.** *See* Ex. 1, CVR Agreement; *See* Ex. 15, SAN-CVR 022060930 at 930.

500. **Sanofi's current CEO, Oliver Brandicourt, testified that if Sanofi's finance staff was looking for ways "not to pay" the CVR that would be "unethical."** Ex. 25, Brandicourt Dep. Tr. at 64:4-64:7; 65:22-66:2.

I. [redacted]

501. [redacted]

502. [redacted]

504. [redacted]

505. [redacted]

506. [redacted]

[redacted]

VII. In the Months After the Merger, Sanofi Delayed Taking Any Actions Toward Achieving the Production Milestone, Causing Sanofi to Miss this Target

A. Fabrazyme® and Cerezyme® Background Information

507. [redacted]

508. **Gaucher Disease is a rare genetic disorder that results in the buildup of certain fatty substances in certain organs, often the spleen and liver. This accumulation causes the organs to grow much larger than normal and can impair their function. The fatty substances associated with Gaucher Disease also can build up in bone tissue. This weakens the bone and increases the risk of fractures. If the bone marrow is affected, it can interfere with the blood's ability to clot. Gaucher Disease is the result of an inherited deficiency in an enzyme that is responsible for breaking down the fatty substance at issue.** *See* Ex. 269, Cerezyme® at 1, available at https://www.cerezyme.com (last visited June 27, 2019); *see* Ex. 279, *Genetics Home Reference: Gaucher disease*, NATIONAL INSTITUTE OF HEALTH, available at https://ghr.nlm.nih.gov/condition/gaucher-disease (last visited June 27, 2019); *see also* Ex. 271, *What Is Gaucher Disease?*, NATIONAL GAUCHER FOUNDATION at 1, available at https://www.gaucherdisease.org/about-gaucher-disease/what-is (last visited June 27, 2019).

509. **Imiglucerase is a recombinant version of that enzyme, developed by Genzyme. In 1994, imiglucerase was approved for the treatment of Type I Gaucher Disease. It is sold under the tradename Cerezyme®.** *See* Ex. 272, *Proposed Text of the Labelling of the Drug, Cerezyme* at 1 (Mar. 2003), available at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/20367s066lbl.pdf.

510. [redacted]

511. [redacted]

512. **Fabry Disease is a rare genetic disorder that results in the buildup of certain fatty substances in blood vessel walls throughout the body. The primary defect which allows this to occur is the inherited deficiency of an enzyme normally responsible for the breakdown of this fatty substance.** *See* Ex. 273, Fabrazyme□, available at https://www.fabrazyme.com (last visited June 27, 2019); *see also* Ex. 274, *What is Fabry Disease*, FABRY SUPPORT & INFORMATION GROUP (FSIG) at 1, available at http://www.fabry.org/fsig.nsf/pages/fabry (last visited June 27, 2019).

513. [redacted]

514. [redacted]

515. [redacted]

516. **Between 2011 and 2018, Sanofi has realized over €9.4 billion from sales of Cerezyme® and Fabrazyme®.** *See* Ex. 20, Sanofi Form 20-F 2018 at 90 (Cerezyme sales

reached €711 million in 2018, and €731 million in 2017, while Fabrazyme sales reached €755 million in 2018, and €722 million in 2017); *see* Ex. 21, Sanofi Form 20-F 2016 at 95, 114 (Cerezyme sales reached €748 million in 2016, €757 million in 2015, and €715 million in 2014, while Fabrazyme sales reached €674 million in 2016, €592 million in 2015, and €460 million in 2014); *see also* Ex. 22, Sanofi Form 20-F 2013 at F-108 (Cerezyme sales reached €688 million in 2013, €633 million in 2012, and €441 million in 2011, while Fabrazyme sales reached €383 million in 2013, €292 million in 2012, and €109 million in 2011.)

B. Sanofi Knew of Manufacturing Issues with Cerezyme® and Fabrazyme® Prior to the Merger

517. **In June 2009, Genzyme announced that it had identified viral contamination in the equipment at its Allston, Massachusetts facility.** *See* Ex. 276, *Press Release: Genzyme Reports Progress Related to Allston Plant,* SANOFI-GENZYME at 1 (June 25, 2009), available at https://news.genzyme.com/press-release/genzyme-reports-progress-related-allston-plant; *see also* Ex. 268, MYDS SANOFI 000107 at 114.

518. [redacted]

519. [redacted]

520. [redacted]

[redacted]

521. [redacted]

- [redacted]
- [redacted]
- [redacted]
- **In its March 30, 2011 prospectus pursuant to 424(b)(3), Sanofi identified "its expectation that Parent's [Sanofi] management and manufacturing personnel can successfully assist in restoring Genzyme's manufacturing processes to full production and restore Genzyme's market share in the rare disease market."** Ex. 14, SEC, EDGAR, Prospectus Filed Pursuant to Rule 424(b)(3), Reg. No. 333-172638 at 39, available at https://www.sec.gov/Archives/edgar/data/1121404/000119312511082363/d424b3.htm (last visited Aug. 30, 2019).

522. [redacted]

523. [redacted]

524.

525.

526.

C.

527.

528.

529. **Christopher Viehbacher testified on examination from his counsel that "because production leadership was focused on fixing the problems at Cerezyme -- for Cerezyme and Fabrazyme, we felt that we shouldn't undertake any integration activities within the production division because that could risk distraction on fixing the Fabrazyme and Cerezyme issues."** Ex. 26, Viehbacher Dep. Tr. 326:8-326:14.

530.

[redacted]

531. **Sandra Poole, then Allston Manufacturing Site Head , could not "recall any conversation about the CVR with Sanofi."** Ex. 287, August 29, 2018 Videotaped Deposition of Sandra Poole ("Poole Dep. Tr.") at 179:12-179:17.

532. [redacted]

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

533. [redacted]

[redacted]

534. [redacted]

535. [redacted]

536. [redacted]

537. [redacted]

538. [redacted]

539. [redacted]

540. **In summer 2011, Sanofi revised Allston's production goals, untethering them from the requirements of the Production Milestone "once it was clear and everybody understood that there was no possibility of achieving the CVR targets."** *See* Ex. 287, Poole

Dep. Tr. at 247:2-248:12.

541. [redacted]

542. [redacted]

543. [redacted]

- [redacted]
- **Sandra Poole testified that in August 2011, Eric Berger began to have one-on-one meetings with Genzyme personnel to discuss manufacturing improvements.** *See* Ex. 287, Poole Dep. Tr. at 286:15-287:8.
- [redacted]
- [redacted]
- [redacted]

544. **The Production Milestone set a target of 734,600 400 Unit Vial Equivalents of Cerezyme with a December 31, 2011 deadline.** Ex. 1, CVR Agreement § 1.1, definition of "Production Milestone"; § 7.10.

545. [redacted]

546. **The Production Milestone set a target of 79,000 35-milligram Vial Equivalents of Fabrazyme with a December 31, 2011 deadline.** Ex. 1, CVR Agreement § 1.1, definition of "Production Milestone"; § 7.10.

547. [redacted]

548. **"Production Milestone Payment Date' means, with respect to the Production Milestone, the date that is twenty (20) Business Days following the date of achievement of the Production Milestone, but no earlier than January 3, 2012."** Ex. 1, CVR Agreement § 1.1, definition of "Production Milestone".

Dated: September 13, 2019

CAHILL GORDON & REINDEL LLP

By: /s/ Charles A. Gilman
Charles A. Gilman
Tammy L. Roy
Jonathan D. Thier
Michael B. Weiss
Adam S. Mintz
Brent L. Andrus
Margaret Barone
Caroline Saucier
80 Pine Street
New York, New York 10005

(212) 701-3000
cgilman@cahill.com
troy@cahill.com
jthier@cahill.com
mweiss@cahill.com
amintz@cahill.com
bandrus@cahill.com
mbarone@cahill.com
csaucier@cahill.com

Attorneys for Plaintiff UMB Bank, N.A., as Trustee